UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,050	08/23/2001	Yoav Blatt	BLATT-2	7772

7590 12/09/2004

BROWDY AND NEIMARK, P.L.L.C.
624 Ninth Street, N.W.
Washington, DC 20001

EXAMINER	
PRATT, HELEN F	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,050	BLATT ET AL.	
	Examiner	Art Unit	
	Helen F. Pratt	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8-11, 13, 14, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al. (3,565,559) in view of Silbiger et al. GB 1192171 and Kantor et al. (4,895,725) and Patel et al. (6,569,463).

Sato et al. disclose a method of making a microencapsulated composition by forming an aqueous emulsion, adding a surface active agent, dispersing, then adding a gelable hydrophilic substance (alginate) forming droplets, adding multivalent ions to cause gelation adding a electrolyte, washing, and dehydrating the microcapsules, separating and drying the capsules (col. 2, lines 25-73, col. 3, lines 15-28). The lipophilic compound is seen to have been reduced in size by the emulsification process as in step (i). (col. 3, lines 34-50). The alginate is combined with the emulsion containing the oil and surfactant (col. 3, lines 50-55, 65-68). The lipophilic compound can be vitamin A (claim 6). Claims 1, 4 and 6 differ from the reference in the step of adding dropwise the second composition to a solution containing calcium to obtain beadlets. However, Silbiger et al. GB 1192171 discloses a method of making beads from alginate by dropping the alginate solution into a solution which will coagulate the alginate and provide a hard shell (abstract and page 1, lines 8-18). Claim 1 further differs from the reference in rinsing the beadlets in acid solution and drying. Kantor et al. discloses atomizing an emulsion into an

acidic solution. Drying is disclosed by Sato et al. (col. 6, lines 30-34). Patel et al. disclose that it is known to coat a beadlet (col. 41, lines 55-65, col. 42, lines 14-36, col. 52, lines 44-55 and col. 60, lines 30-33, and 44-49). Therefore, it would have been obvious to reduce the size of a lipophilic compound in the presence of a surfactant when combining it with an alginate material, because the primary reference is also combining lipophilic compounds with alginate, and it would have been obvious to rinse the beadlets with an acid as disclosed by Kantor and to further coat as disclosed by Patel et al.

Claims 2 and 3 and 15-18 further require a particular particle size. Sato et al. disclose particle sizes of from 0.5 to 10,000 microns (col. 6, lines 35-44). Therefore, it would have been obvious make microcapsules of the claimed size as disclosed by Sato et al.

Claim 9 requires particular acids. Kantor discloses acids as above. Kantor et al. disclose acids such as ascorbic and lactic acid as claimed (col. 6, lines 39-44). Therefore, it would have been obvious to use acids, which are food safe in the process of Sato et al.

Claim 10 requires particular coating materials and claim 11 hydroxpropylcellulose. No difference is seen in the use of hydroxypropylcellulose and a different derivative of cellulose, and that of claim 11 at this time since they are both used for coating (col. 46, lines 5-14, and lines 35-45). Therefore, it would have been obvious to coat with known celluloses.

The limitations of claim 13 –14, 20, 21 have been discussed above and are obvious for those reasons.

Claim 22 requires that the composition is tablet grade. However, it would have been obvious to use ingredients to meet particular specifications.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the above combined references as applied to the above claims and further in view of Francois et al. (6,555,544).

Water can be in the composition as in claim 12 for size reduction as in step I as disclosed in the reference to Francois et al. (col. 8, lines 44-50). Therefore, it would have been obvious to use water in the size reduction step.

Claims 5, 7, 19, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above combined references as applied to the above claims, and further in view of Lim et al. (4,389,419).

Lim et al. disclose a process of encapsulating oils and oil soluble substances in microcapsules by forming an emulsion of alkali metal alginate and a filler such as a polysaccharide and an oleophilic substance such as a vitamin, then treating with a solution containing calcium to form beadlets which are washed and dried (abstract and col. 1, lines 34-64). Claim 5 further requires that a filler be added to stage 1 and claim 7 that it is added at stage ii. Lim et al. disclose that a polysaccharide such as dextrin can be added with the alginate or carboxymethyl cellulose, starches which would have been at stage 2. (col. 2, lines 30-49). Nothing new is seen in adding yet another ingredient to be ground as in stage 1 to achieve the same particle size. Therefore, it would have been obvious to add a filler at stage 1 or 2.

Claim 19 further requires particular amounts of lipophilic compound in the mixture. Lim et al. disclose the use of from 1-10% vitamin or oil (col. 2, lines 58-63) and Francois et al. disclose the use of a palmitate anti-psychotic agent which is about 3% fat (col. 8, lines 60-70). Therefore, it would have been obvious to use a lipophilic compound in the claimed amounts.

Claim 23 is to using the lipophilic compounds in food stuff. Lim et al. disclose that their encapsulated vitamins can be used in a foodstuff. Therefore, it would have been obvious to add the composition of the combined references to a foodstuff for the known function of adding at least fat to the foodstuff.

Claim 24 further requires masking the flavor or smell of the fat compound by encapsulating as claimed. However, as the claimed composition has been shown as above, it is obvious that the flavor would have been inherently masked.

Claim 25 further requires making an emulsion of water and the lipophilic compound. Sato et al. disclose making an emulsion of vitamin A in an aqueous emulsion (abstract) and col. 2, lines 24-35). The active chemical substance of the reference (vit. A) is seen to the required lipophilic compound of the reference. The further limitations of the claim have been disclosed above and are obvious for those reasons.

ARGUMENTS

Applicant's arguments filed 11-5-04 have been fully considered but they are not persuasive. Applicants argue that the claims should be allowed as they had been previously allowed even though a Search report was submitted in an RCE. However, the Examiner would have been remiss not to have applied the references and make of record any arguments.

Applicants argue that a relatively large amount of lypophilic material can be incorporated into the microcapsule while retaining high bioavailability, and that the references to Sato and Silbiger do not add anything. However, no amount of lypophilic material is claimed in claim 1. The limitations disclosed as to Sato et al. and Silbiger et al. have been disclosed. Nothing is seen as to three coating layers as argued or a particular particle size in claim 1. Sato et al.

disclose particle sizes within the claimed range. Applicants as in claims 2 and 3 have claimed particular sizes, but the method of making such is known. Applicants also claim large sizes of from 100 to 425 um as in claim 8.

The motivation to combine the references is that all the limitations are known and have been disclosed in the combined references. Certainly, various references can be used to show the claimed limitations when the independent claim 1 is a page long. Again, no amount of lypophilic content has been claimed.

Applicants admit that the additional references only show minor features. Certainly, it is proper to show to use these references to show the claimed features, else applicants would have argued that they were novel.

Applicants argue that the range of sizes in Sato is so large that it would not have been obvious to make microcapsules. This is not seen when the references states plainly that the claimed size is known. In addition, applicants also claim larger sizes of microcapsules.

Applicants argue as to Francois only that it does not make up for deficiencies in the other references. However, it is used for what it teaches.

Applicants argue that the rejection is ambiguous as to claims 5, 7, 19, 23-25. The rejection of claims 5,7, 19, 23-25 relies on the first combination since none of these claims depend on claim 12.

Applicants argue as to the superior product, and large amount of lipophilic material, but no showing has been made as to such or a limitation made as to the amounts of lipophilic material.

It is not seen that a plurality of coatings would have affected the bioavailability of the encapsulated material, particularly, as the claimed coatings have been shown.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hp 12-7-04

H. Pratt

HELEN PRATT
PRIMARY EXAMINER